

**OPTN/UNOS Ad Hoc International Relations  
Committee Meeting**

**August 7, 2007 and September 28, 2007  
Teleconference and Live Meeting**

***INTERIM REPORT***

**Andreas Tzakis, MD – Chair  
Gloria Bohrer – Vice Chair**

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The OPTN/UNOS Ad Hoc International Relations Committee met on August 7, 2007. At this meeting, the Committee did not complete its discussion of the majority of items on the agenda, and so, met again on September 28, 2007 to complete deliberations on these remaining agenda items.

**1. Committee Annual Goals**

The Committee discussed the following Annual Goals and explored methods for meeting them in the next year.

- a. The Committee will explore streamlining the importation of an organ from another country by focusing on the following issues: 1) legitimacy of the foreign organization offering the organ; 2) testing/safety of the foreign organ being offered; 3) rules of distribution of organs between countries; and, 4) explore developing an exemption to Policy 6.3.

The Committee decided that for sub-goals 1-3, they will review existing, relevant OPTN policies to determine whether the language needs to be strengthened to meet these goals. The intent of these three goals is to ensure that the foreign organizations offering the organs are legitimate, and that the organs offered are medically safe for transplant. These topics have been discussed by the Committee in the past. UNOS staff will research whether the foreign organs offered to an organ procurement organization (OPO) in the US are distributed using a national or local match-run.

With respect to sub-goal 4, the Committee will explore in the next year an exemption to Policy 6.3 that might accommodate the following scenario: If organs are offered to a US transplant center X from country Y, then the US transplant center X would transplant a non-resident alien recipient who is a national of country Y. This reciprocal offer from the US transplant center X would be exempt from the audit outlined in Policy 6.3. In the next year, the Committee will review evidence that would support or not support this concept.

- b. The Committee will maintain the public's trust in the organ allocation system by investigating questionable allocation events, and maintaining complete transparency in the organ transplantation process.

The Committee discussed that this goal is really its "modus operandi," and that to continue to achieve this goal, it is important to also ensure the accuracy of the data presented to the community.

- c. The Committee will review the number of organs exported from and imported to the US.

UNOS staff will provide the Committee, at the next full meeting, the number of organs imported and exported in 2006/2007. This data request is a Committee charge from the OPTN President, Dr. Tim Pruett.

- d. The Committee will explore identifying the number of Americans who travel overseas for transplants (charge from Dr. Pruett).

The Committee considered possible methods for obtaining these data. UNOS staff stated that a review of data collected during waitlist removal might provide some information. In the

list of reasons for removing a candidate from the waitlist, there is an “other” category that can be completed. Often, if the reason for removal is a transplant in another country, this reason is provided here.

Another approach is to circulate a questionnaire to transplant centers for information about candidates who travel overseas for transplant, as well as about recipients seeking post-transplant care after having received a transplant overseas. The SRTR reported of a transplant tourism study they had presented at the 2007 American Transplant Congress. The SRTR reviewed the “other” OPTN data field referenced above, and sent a questionnaire to transplant centers identified from that method as well as those with waiting list removals for transplant where the corresponding transplant event could not be identified. The SRTR will share this abstract with the Committee at the meeting.

The Committee inquired about the possibility of requiring the candidate to state the country in which they were going to be transplanted. This data collection effort might provide numbers about the scope of transplant tourism practiced by American transplant waitlist candidates. UNOS staff will review this possibility and present information about it at the next full Committee meeting. One Committee member suggested inviting Dr. Francis Delmonico, who is affiliated with the Advisory for Human Transplantation of the World Health Organization, to discuss the global scope of transplant tourism.

UNOS staff stated that in June, 2007, the OPTN Board of Directors approved a statement on transplant tourism that included a statement that the medical community is obligated to care for patients returning to the US after having received a transplant overseas. This statement’s effects on the community might facilitate future data collection on the number of American recipients who seek care in the US after receiving a transplant overseas.

*Action Item*

- UNOS staff will forward these annual goals as final Committee goals to Dr. Pruett.
- UNOS staff will research the information relevant for accomplishing the annual goals.
- At the next meeting, UNOS staff will provide data on the number of organs imported to and exported from the US.
- UNOS staff will coordinate Dr. Delmonico’s participation at the next Committee meeting.
- SRTR will share the ATC study with the Committee at the next Committee meeting.

**2. Meeting the HHS Program Goals**

UNOS staff updated the Committee on the efforts of OPTN, in 2006, to achieve the HHS program goals. The intent of the HHS goals is to increase the number of donors, organs transplanted, and organs transplanted per donor. Each year since 2004, the OPTN has met the goal for the total number of non-DCD deceased donors. In 2006, the OPTN exceeded its goal. The OPTN did not meet its goal for the total number of DCD donors, but it did experience a substantial increase in the number of DCD donors. Reaching this goal would have required an increase of 42% from the 2005 number. The national rate for organs transplanted per non-DCD donor in 2006 was 3.13, lower than the goal of 3.44. However, when only considering standard criteria non-DCD donors, the national rate was 3.44; the rate for expanded criteria donors was much lower. The OPTN did not meet the HHS goal of 2.33 for organs transplanted per DCD donor. The OPTN’s rate was 2.11, but there were some donation service areas (DSAs) that surpassed the 2.33 goal.

**3. Data Report: Pediatric Resident and Non-Resident Alien Recipients and Donors**

In August, 2006, the OPTN/UNOS Pediatric Committee had requested the Ad Hoc International Committee to comment on the transplantation of illegal aliens, especially as it applies to pediatric candidates in the United States. (These 8/7 and 9/28 meetings have been the Committee’s first since August, 2006.)

UNOS staff reported that there is limited data collected on donor and transplant recipient citizenship status. OPTN does not collect data on a donor's or candidate's legal residence status. OPTN has the following information about the donor's or candidate's citizenship status: US citizen; non-US citizen, resident alien; and, non-US citizen, non-resident alien. The subsequent analysis was on the transplants performed and deceased donors recovered, by these three citizenship groupings. The analysis incorporated data collected during 2002-2006.

Of the total number of non-resident alien transplant recipients during 2002-2006, a higher percentage of them were pediatric patients. The age distributions in the U.S. citizen and resident alien transplants show less variation.

With respect to donation, overall, the number of non-US citizen donors has decreased over the last five years. The most substantial decrease is in the number of resident alien donors, which has decreased from a high of 233 in 2003 to 79 during 2006. The number of non-resident alien donors has remained more stable over the past five years, with a high of 56 in 2003 and a low of 43 in 2006. Among the US citizen deceased donor population, during this period, the pediatric age-group comprised over 13% of the total. However, this proportion is much smaller for the resident and non-resident alien donors, where pediatric donors comprise 5.4% and 6.0% of the total, respectively.

This analysis could not address data by a candidate's legal or illegal status, as requested by the Pediatric Committee, because this legal data are not collected currently. Collecting this information in the future, however, may have unintended consequences in the area of donation advocacy. Even if the legal status could be collected, the accuracy of the collected information may be questionable.

*Action Item*

- UNOS staff will forward these data, as well as the Committee's discussion of them, to the Pediatric Committee.

**4. Data Report: Donors with Organs Exported from the United States**

At its August, 2006 meeting, the Committee had requested data on organ exports, including characteristics of the donors whose organs were exported and the disposition of these organs.

UNOS staff reported that between January, 2002 and April, 2007, there were 231 organs exported nationally. Of these, nearly all (95%) of the organs exported were thoracic organs (121 hearts; 99 lungs). A high percentage of these thoracic organs were from pediatric donors. Many of the thoracic organs were recovered in Alaska, where the cold-time restrictions necessitated an export to Canada. Regions 5 and 10 were the primary exporters of thoracic organs. Exported hearts were primarily from donors less than 6 years of age. The rate of organs transplanted per donor, from whom a heart was exported, was 3.9. In this group, there were 6 donors where 6 organs were transplanted. There were also 7 cases where the heart was not ultimately transplanted.

With respect to lungs, Region 5 was the primary exporter. Regions 2, 10, 6, and 9 also exported lungs. The lungs were from primarily adult donors.

Canada received all the exported organs in this analysis.

Of the non-thoracic organs exported, there were 5 livers exported in this time period. Of these, 4 were exported in 2006. Also, 4 of the 5 livers were recovered from donors less than 6 years of age. Various regions exported the non-thoracic organs.

This number of exported organs might be reflecting the aggressive placement efforts of the OPOs recovering these organs.

*Action Item*

- UNOS staff will provide data on the number of organs imported at the next full Committee meeting, as requested by the Committee during the discussion of annual goals.

## **5. Gift of Life of Michigan**

The Ad Hoc International Relations Committee did not discuss the Gift of Life of Michigan's organ export practice. UNOS staff advised the Committee that this organ export practice needed to be considered by organ allocation committees as an alternative allocation system. Essentially, the Gift of Life of Michigan is not exhausting the national wait list before exporting organs to Canada. This practice does not follow Policy 6.4. As a result, a discussion of this topic did not fall within the purview of the Ad Hoc International Relations Committee.

*Action Item*

- UNOS staff will convey to the Gift of Life of Michigan that the Committee did not discuss their organ export practice.

## **6. Legal Standpoint on Ethics of Disclosing Donor-Donee Relationships**

The Committee received the following question from an individual residing outside of the United States:

[...] "I request your opinion on one remedy that we are considering to curb illegal kidney retrieval from live unrelated donors which is being opposed by some doctors as infringing "medical ethics". We wish to publish names / addresses of prospective donors and intended donees in newspapers and enforce a stipulated waiting period before scheduling surgery. It is our contention that this would give civil society a reasonable chance to uncover fake "affection" and illegal payments. " [...]

The Ad Hoc International Relations Committee determined that the ethical question described above is more appropriate for consideration by the OPTN/UNOS Ethics Committee. The Committee did not discuss this issue, and will forward this issue to the Ethics Committee.

*Action Item*

- UNOS staff will forward the ethical question described above to the Ethics Committee.

## **7. Clarification of Policy 6.2.5**

The Committee reviewed a request from a transplant community member to clarify the intent of the phrase "mechanism for community participation" in Policy 6.2.5 below.

*6.2.5 Community Participation. Each member center which lists non-resident aliens on its Waiting List should establish a mechanism for community participation and review of its candidate acceptance criteria.*

The Committee discussed the possible interpretations of the phrase. Within the Committee, there were some differing interpretations of this phrase. One member considered this language as encouragement for initiating dialogue about improving transplantation practices in the communities of origin of non-resident alien transplant candidates. If these candidates are coming to the US for transplant because they are not being accepted for this procedure in their home countries, then one effort of this dialogue would be to broaden the transplant acceptance criteria in the given foreign country.

Another member interpreted “mechanism for community participation” as the transplant center’s opportunity to engage the local community (public, not transplant professional) in a dialogue about their candidate acceptance practices as they apply to non-resident aliens.

UNOS staff stated that the original intent of this policy is to generate transparency of and public participation in the OPTN process. In the past, there were discussions about developing separate lists for separate citizen classes, and the community decided that one list for all citizen groups would be best. Within this one list, there is a maximum rate associated with the number of non-resident aliens a center may transplant annually (Policy 6.3).

The Committee discussed two approaches for clarifying the intent of “mechanism for community participation”. One proposed method for clarifying this policy is to query the OPTN community on their current understanding of this phrase. Another method was to provide a definition, stemming from within the Committee, of “mechanism for community participation.” The Committee preferred the latter approach. UNOS staff will draft this language for review at a future meeting. This definition should convey that the intent of the dialogue is to communicate how and why transplant center candidate acceptance practices apply to non-resident aliens. This language should include an example of how to carry out the policy.

*Action Item*

- UNOS staff will draft the revised policy language and present it at a future Committee meeting.

## **8. Review of Public Comment Proposals**

*Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (2)  
Kidney Transplant Programs that Perform Living Donor Kidney Transplantation*

The Ad Hoc International Relations Committee met via telephone conference call on August 7, 2007, and discussed this proposal as part of its full committee meeting. Since the scope of this proposal falls outside of its purview, the Committee decided to submit a “No Comment” as feedback for the MPSC and Living Donor Committee (4-No Comment; 0-Support; 0-Oppose; 0-Abstain).

*Proposed Modifications to OPTN/UNOS Bylaws, Appendix B, Attachment I, Section XIII, C (4)  
Liver Transplant Programs that Perform Living Donor Liver Transplants (Membership and Professional Standards and Living Donor Committees)*

The Ad Hoc International Relations Committee met via telephone conference call on August 7, 2007, and discussed this proposal as part of its full committee meeting. Since the scope of this proposal falls outside of its purview, the Committee decided to submit a “No Comment” as feedback for the MPSC and Living Donor Committee (4-No Comment; 0-Support; 0-Oppose; 0-Abstain).

*Guidelines for the Medical Evaluation of Living Kidney Donors (Living Donor Committee*

The Ad Hoc International Relations Committee met via telephone conference call on August 7, 2007, and discussed this proposal as part of its full committee meeting. The Committee “Abstained” from making any supporting or opposing comments (0-Support; 0-Oppose; 4-Abstain). The Committee, however, did provide the following suggestions, and would like to see these incorporated into the current proposal:

- These consent guidelines that pertain to living donors who are US citizens should also pertain to foreign nationals who come into the United States and are accepted as living donors.
- US transplant centers that perform transplants from living donors who are foreign-nationals should have a mechanism in place to follow-up and evaluate this living donor, in the same way they would for the living donor who is a US citizen.

*Guidelines for the Consent of Living Donors (Living Donor Committee)*

The Ad Hoc International Relations Committee met via telephone conference call on August 7, 2007, and discussed this proposal as part of its full committee meeting. The Committee "Abstained" from making any supporting or opposing comments (0-Support; 0-Oppose; 4-Abstain). The Committee, however, did provide the following suggestion, and would like to see this incorporated into the current proposal:

- These consent guidelines that pertain to living donors who are US citizens should also pertain to foreign nationals who come into the United States and are accepted as living donors.

*Action Item*

- UNOS staff will forward the Committee's discussion and vote on the proposals above to the relevant sponsoring Committee's liaison.

<b>Ad Hoc International Relations Committee</b>	<b>August 7, 2007 Teleconference and Live Meeting (Discussed Remaining Agenda Items on September 28, 2007)</b>	
<b>Name</b>	<b>Position</b>	<b>Attendance</b>
Andreas G. Tzakis, MD, PhD	Chair	By phone
Gloria Garcia Bohrer	Vice Chair	By phone
Victor Ankoma-Sey, MD	At Large	
David R Grant, MD	At Large	By phone
Marian A. O'Rourke, RN, CCTC	At Large	By phone
Myron E. Schwartz, MD	At Large	
Tatiana Alvarez, RN, BSN, CCTC	At Large	
Nancy Carothers, RN	Ex Officio – HRSA	By phone
Jade Perdue	Ex Officio – HRSA	
Diane Steffick	SRTR Liaison	By phone
Vipra Ghimire	Committee Liaison	By phone
Doug Heiney	Committee Liaison	By phone
Sarah Taranto	Support Staff	By phone
Judy Martin	Support Staff	By phone
Stacey Burson	Support Staff	By phone
Chrystal Oley-Graybill	Support Staff	By phone
Catherine Monstello	Support Staff	By phone

<b>Ad Hoc International Relations Committee</b>	<b>September 28, 2007 Teleconference and Live Meeting</b>	
<b>Name</b>	<b>Position</b>	<b>Attendance</b>
Andreas G. Tzakis, MD, PhD	Chair	By phone
Gloria Garcia Bohrer	Vice Chair	By phone
Victor Ankoma-Sey, MD	At Large	
David R Grant, MD	At Large	
Marian A. O'Rourke, RN, CCTC	At Large	By phone
Myron E. Schwartz, MD	At Large	
Tatiana Alvarez, RN, BSN, CCTC	At Large	By phone
Nancy Carothers, RN	Ex Officio – HRSA	By phone
Diane Steffick	SRTR Liaison	By phone
Vipra Ghimire	Committee Liaison	By phone
Doug Heiney	Committee Liaison	By phone
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